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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,706	01/28/2005	Verena Stangl	2958-128	7467

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EXAMINER	
BRADLEY, CHRISTINA	

ART UNIT	PAPER NUMBER
1654	

NOTIFICATION DATE	DELIVERY MODE
12/13/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Advisory Action Before the Filing of an Appeal Brief	Application No.	Applicant(s)	
	10/522,706	STANGL ET AL.	
	Examiner	Art Unit	
	Christina Marchetti Bradley	1654	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 21 November 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): 112, first paragraph, enablement; 112, second paragraph and 103.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: *6-9 and 30*.
   Claim(s) rejected: *1-5, 27-29*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

1. Claims 1-9 and 27-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. To provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of compete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof.

2. Claims 1-9 and 27-29 are drawn to proteosome inhibitors. The specification discloses the complete structure of MG132, MG115, LLnL, PS1, carbobenzoxy-L-leucinyl-L-leucinyl-L-leucin-vinyl-sulfon, NLVS, pyrazyl-CONH(CHPhe)CONH(Chisobutyl)$B(OH)_2$, benzyloxycarbonyl(Cbz)-Leu-leuboro-Leu-pinacol-ester, PS-314, PS-519, aclacinomycin A, lactacystin, clastolactacystein, PS-273, PS-293, PS-296, PS-303, PS-321, PS-334, PS-352, PS-383, PS-341, PS-1, PS-2, PS-519, epoxomicin, eponenycin, catchin-3-gallate, DFLB, MG273, SEQ ID NOs: 2-5, dihydroeponemycin, omuralid, ALLN, DCI, pefaclock SC, TMC-95-A, gliotoxin, EGCG, ritonavir, lovastatin, aclarubicin, and cyclosporin as examples of proteosome inhibitors. The claims are also drawn to the following partially-defined structures: peptide aldehydes, peptide boronates, peptide vinylsulfones, peptide epoxyketones, peptide α-ketonaldehyde, indanonpeptides, peptide derivatives with C-terminal expoxy keton structures, and modified peptide aldehydes. The minimal structural requirements for these classes of compounds are that they include a peptide sequence and an aldehyde, boronate, vinyl sulfone ,

epoxyketone, ketoaldehyde, or C-terminal epoxy ketone. An infinite number of peptide compounds could satisfy these minimal requirements. The specification fails to provide additional information about the physical/chemical properties and structure/function relationship for peptide sequences that fall within the genus of proteosome inhibitors. Likewise, the minimal structural requirements for α-ketonamides, polyalkylenaldehydes, polyphenols, β-lacton-derivatives, glyoxal residues and boric acid residues, to which the claims are also drawn, are that the compounds include these chemical moieties plus any additional structure. The specification fails to provide additional information about the physical/chemical properties and structure/function relationship for α-ketonamides, polyalkylenaldehydes, polyphenols, β-lacton-derivatives, glyoxal residues and boric acid residues that fall within the genus of proteosome inhibitors. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

3. With the exception of MG132, MG115, LLnL, PS1, carbobenzoxy-L-leucinyl-L-leucinyl-L-leucin-vinyl-sulfon, NLVS, pyrazyl-CONH(CHPhe)CONH(Chisobutyl)$B(OH)_2$, benzyloxycarbonyl(Cbz)-Leu-leuboro-Leu-pinacol-ester, PS-314, PS-519, aclacinomycin A, lactacystin, clastolactacystein, PS-273, PS-293, PS-296, PS-303, PS-321, PS-334, PS-352, PS-383, PS-341, PS-1, PS-2, PS-519, epoxomicin, eponenycin, catchin-3-gallate, DFLB, MG273, SEQ ID NOs: 2-5, dihydroeponemycin, omuralid, ALLN, DCI, pefaclock SC, TMC-95-A, gliotoxin, EGCG, ritonavir, lovastatin, aclarubicin, and cyclosporine, the skilled artisan cannot envision the detailed chemical structure of the proteosome inhibitor. Although the minimal structural requirements of the broad genus are defined, there are too many undefined structural

features for the skilled artisan to know specifically which compounds possess the claimed functional characteristics. Therefore, these specifically recited compounds, but not the full breadth of the claims, meet the written description provision of 35 U.S.C. §112, first paragraph.

Allowable Subject Matter

4. Claims 6-9 and 30 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

5. No claims are allowed.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christina Marchetti Bradley whose telephone number is (571) 272-9044. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M.

7. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

8. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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